UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DURK PEARSON and SANDY SHAW, ET AL.,	:	
Plaintiffs	:	
v.	:	**Civil Action No. 95-1865 (GK)**
DONNA E. SHALALA, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,	:	
Defendants.	:	

MEMORANDUM OPINION

This matter is before the Court on Defendants' Motion to Dismiss [#12], and Plaintiffs' Motion for Summary Judgment [#28]. Plaintiffs, Durk Pearson and Sandy Shaw, the American Preventive Medical Association, Citizens for Health, and the National Health Federation, challenge the constitutional validity of several U.S. Food and Drug Administration ("FDA") regulations that require sellers of dietary supplements to obtain FDA authorization before labeling such supplements with "health claims".[1] Plaintiffs are manufacturers, distributors and organizations of consumers of dietary supplements.

Plaintiffs challenge both the general rule issued by FDA for

[1] Health claims are statements that describe a relationship between a nutrient, such as calcium, and a disease or health-related condition, such as osteoporosis. See 21 U.S.C. § 343(r)(1)(B) (1996).

determining the validity of health claims for dietary supplements, 21 C.F.R. § 101.14, as well as four separate regulations addressing claims for specific disease-nutrient relationships, issued pursuant to that general rule under the Nutrition Labeling and Education Act of 1990 ("NLEA"), Pub. L. 101-535, 104 Stat. 2353 (1990). Plaintiffs claim that the regulations violate the First Amendment, violate the Fifth Amendment because they are unconstitutionally vague, and violate the NLEA and the Administrative Procedure Act ("APA"), 5 U.S.C. § 706 (1996). Plaintiffs seek review of the Final Rules of the FDA, which established the general health claim standard and denied approval for labeling containing the four specific health claims, as well as a declaratory judgment and injunctive relief.

All Defendants (Donna E. Shalala, Secretary, Department of Health and Human Services ("HHS"), HHS itself, David A. Kessler, Commissioner of the FDA, the FDA itself, and the United States of America) move to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), for failure to state a claim upon which relief can be granted. Upon consideration of Defendants' and Plaintiffs' Motions, Oppositions, Replies, Amici Curiae Memoranda, and the entire record herein, for the reasons discussed below, the Court **grants** Defendants' Motion to Dismiss, and **denies** Plaintiffs' Motion for Summary Judgment.

I. Statutory and Regulatory Framework

Prior to enactment of the NLEA, which amended the Federal

Food, Drug, and Cosmetic Act ("FFDC Act"), 21 U.S.C. § 301 et seq. (1972), dietary supplements, such as Vitamin C tablets, were regulated as a food, unless their intended use was as a drug.[2] If a dietary supplement's label contained a disease-specific health claim, that supplement became subject to the FDA's drug approval and drug labeling requirements. See H.R. Rep. No. 538, 101st Cong., 2d Sess. at 9 (1990), reprinted in 1990 U.S.C.C.A.N. 3338 ("House Report"); 21 U.S.C. §§ 321(g)(1)(B) and 355 (1996).[3]

During the mid-1980s companies began making health claims about foods without the approval of the FDA. See House Rep. at 9; see e.g. Kellogg Co. V. Mattox, 763 F. Supp. 1369 (N.D. Tex. 1991)(breakfast cereal "Heartwise" claimed to lower cholesterol), aff'd mem. sub nom. Kellogg Co. V. Morales, 940 F.2d 1530 (5th Cir. 1991). In order to "clarify and to strengthen [the FDA's] legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods", Congress passed the NLEA. House Report at 7.

The NLEA had two main goals: (1) to help consumers maintain healthy dietary practices by requiring food labeling to contain

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[2] Food is defined, in part, as "articles used for food or drink." 21 U.S.C. § 321(f)(1) (1990). Drugs are defined, in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease." 21 U.S.C. § 321(g)(1)(B) (1996).

[3] A drug must be proven to be safe and effective for its intended uses before marketing. See, e.g., United States v. Rutherford, 442 U.S. 544, 551-52 (1979).

clear, consistent nutrition information, including information about the relationship of diet to disease; and (2) to protect consumers from fraud and misinformation by ensuring that claims made for foods are understandable, consistent, and scientifically valid. House Rep. at 8.

The NLEA liberalized the FFDC Act to permit claims to be "made in the label or labeling of [a] food which expressly or by implication . . . characterize[] the relationship of [a] nutrient . . . to a disease or a health-related condition." 21 U.S.C. § 343(r)(1)(B). The claims, however, must be made in accordance with 21 U.S.C. § 343(r)(3) for foods in conventional form, and in accordance with 21 U.S.C. § 343(r)(5)(D) for dietary supplements. So long as a claim is made in accordance with either one of these two sections, the food or dietary supplement is not subject to the FFDC Act's far more extensive and onerous approval and labeling requirements for drugs. See 21 U.S.C. § 321(g)(1)(B).

In order to assert health claims for conventional foods, the NLEA provides that products must obtain prior FDA authorization. 21 U.S.C. § 343(r)(3)(B)(i). Such claims may be approved:

> only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

Id. (emphasis added). In addition, Congress directed that any

authorizing regulation promulgated by the FDA:

> require such claim to be stated in a manner so that the claim is an accurate representation of [the nutrient-disease relationship] and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

Id. at § 343(r)(3)(B)(iii).

In order to assert health claims for dietary supplements, Congress adopted a slightly different approach. Instead of specifically mandating a particular standard as it did with respect to conventional foods in § 343(r)(3)(B)(i), Congress delegated to the FDA the task of developing a procedure and standard for health claims for dietary supplements. Section 343(r)(5)(D) provides that health claims

> made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such a claim, established by regulation of the Secretary.

Id. (emphasis added). It is the regulation promulgated by the FDA pursuant to this provision which is at issue in this case.

Thus, Congress directed the FDA to establish, through rulemaking, the general health claim procedure and standard to be applied to all dietary supplements, and to determine whether ten specific health claims regarding nutrient-disease relationships in both conventional foods and dietary supplements met the

requirements of the NLEA.[4] Only four of those ten specific nutrient-disease relationship claims are at issue in this case: folic acid and neural tube defects; antioxidant vitamins and cancer; omega-3 fatty acids and coronary heart disease; and dietary fiber and cancer.

II. Procedural History

Following Congress' mandate to issue regulations implementing Section 343(r)(5)(D), the FDA published a proposed rule in the Federal Register on June 18, 1993, defining a standard to evaluate health claims for dietary supplements. The FDA proposed to adopt the same standard for dietary supplements which Congress had already adopted for foods in conventional form in Section 343(r)(3). Plaintiffs submitted comments, arguing that dietary supplements should not be subject to the same procedure and standard as conventional foods, and that the term "significant scientific agreement" should, if adopted, be defined with specificity. (Compl. ¶¶ 52-57.) After extensive proceedings, which included the receipt of comments and hearings to consider Plaintiffs' arguments, the FDA followed its initial approach, used the same standard Congress had already adopted for conventional foods, and defined "significant scientific agreement" on a case-by-case basis. The FDA explained its decision as follows:

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[4] Pub. L. 101-535, as amended Pub. L. 102-571, § 3(b)(1)(A)(vi) & (x) (Oct. 29, 1992).

> [t]he agency believes, however, that any standard involving the evaluation of scientific evidence and opinions derived from that evidence must be somewhat subjective. FDA, in proposing not to define "significant scientific agreement" among experts [citations omitted] noted that each situation may differ with the nature of the claimed substance/disease relationship. The agency believes that in deciding whether significant scientific agreement about the validity of a claim exists, it is necessary to consider both the extent of the agreement and the nature of the disagreement on a case-by-case basis.

48 Fed. Reg. 2506 (1993).

Plaintiffs also filed comments before the FDA objecting to the provisions in the FDA's proposed Final Rules denying approval for the specific health claims Plaintiffs wanted to place on the labels of certain dietary supplements. (Compl. ¶ 27.) In particular, Plaintiffs sought permission for the following health claims on dietary supplement labels: (1) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers" (Compl. ¶¶ 40, 45); (2) "Consumption of dietary fiber may reduce the risk of colorectal cancer" (Compl. ¶¶ 41, 47.); (3) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease" (Compl. ¶¶ 42, 46.); (4) "The U.S. Public Health Service has estimated that fifty percent of neural tube defects may be averted annually if all women maintained an adequate intake of folate during childbearing years";[5] and (5) ".8 mg of folic acid in a dietary supplement is

[5] Plaintiffs' claim on folate and neural tube defects became moot on April 19, 1996, when the FDA issued a Final Rule which eliminated the restriction on the use of the Public Health Service statement, provided that the statement is "accompanied by additional information that states that the estimate is population-

more effective in reducing the risk of neural tube defects than a lower amount in foods in common form." (Compl. ¶¶ 43, 48.)

In the FDA Final Rules, the FDA again rejected Plaintiffs' comments and again prohibited the use of each of Plaintiffs' health claims. (Compl. ¶¶ 28, 44, 49, 50, 51.) Plaintiffs submitted additional comments objecting to the Final Rules issued by the FDA, and filed "Emergency Petitions for Stay of Actions", with supporting scientific evidence. (Compl. ¶¶ 73, 82, 84.) The FDA refused to stay the Final Rules (Compl. ¶¶ 73, 85.), and Plaintiffs filed the instant suit.

III. Analysis

Plaintiffs argue that the central issue in this case is whether the FDA may impose blanket commercial speech bans without adopting procedural safeguards to protect truthful and nonmisleading commercial speech from suppression. Plaintiffs contend that the FDA's general health claim standard for dietary supplements--"significant scientific agreement"--violates the NLEA, APA, First Amendment, and is unconstitutionally vague under the Fifth Amendment. Plaintiffs further argue that since the "significant scientific agreement" requirement constitutes a

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based and that it does not reflect risk reduction that may be experienced by individual women." See 61 Fed. Reg. 8752, 8775-76, 8781; 21 C.F.R. § 101.79(c)(3)(iv) (III Supp. Rec.). This regulation supersedes the rule challenged by Plaintiffs. Defs.' Reply to Pls.' Opp'n to Defs.' Mot. to Dismiss & Opp'n to Pls.' Mot. for Summ. J. at 1 n. 1. Thus, this Court will only address the four remaining health claims.

blanket ban on commercial speech, the FDA's application of this standard also violates the NLEA, APA, and First Amendment, because the FDA has denied approval of the use of four health claims on labels or labeling of certain dietary supplements.

A. Adopting The "Significant Scientific Agreement" Standard For the Labeling of Dietary Supplements Does Not Violate the NLEA or the APA.

Congress directed the FDA, in Section 343(r)(5)(D) of the NLEA, to establish by regulation a procedure and standard for evaluating health claims made with respect to dietary supplements. The agency carried out that statutory directive. It conducted an extensive rule-making proceeding, reviewed thousands of pages of comments on its proposed rules, and reached an independent conclusion that the "significant scientific agreement" standard, which had already received the imprimatur of Congress for purposes of evaluating health claims for conventional foods, was also the most appropriate standard to adopt for purposes of evaluating health claims for dietary supplements. [6]

In the pleadings discussing the legality of the agency's action, all parties recognize that the Court is bound by a highly deferential standard of review. Under the APA, an agency's action may be set aside only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §

[6] The APA argument regarding the "significant scientific agreement" standard is subsumed in the NLEA argument.

706(2)(A). In making this finding, the Court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The Court may not substitute its judgment for that of the agency. Id. Its role is to ensure that the agency's decision was based on relevant factors and not a "clear error of judgment." Id. If the "agency's reasons and policy choices . . . conform to 'certain minimal standards of rationality' . . . the rule is reasonable and must be upheld." Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 521 (D.C. Cir. 1983)(citation omitted). This standard presumes the validity of agency action. Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C. Cir. 1976)(en banc), cert. denied, 426 U.S. 941 (1976).

Courts also give a high degree of deference to agency actions which are, as here, based on an evaluation of complex scientific data within the agency's technical expertise. See Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 103 (1983); NRDC v. EPA, 824 F.2d 1211, 1216 (D.C. Cir. 1987)(citing NRDC v. EPA, 812 F.2d 721, 725 (D.C. Cir. 1987))("[I]t is not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence.")

In explaining its rationale for adoption of the NLEA Final Rules, the agency cited Congress' dual concerns to prevent consumer fraud and promote public health. 59 Fed. Reg. 402-403 (1994). In particular, with regard to adoption of the "significant scientific

agreement" standard, the FDA found that allowing health claims based on a lesser standard would create significant risks to the public health:

> A few studies may often be found about a multitude of [nutrient-disease] associations, and many, if not most, of those associations will ultimately be found not to be valid. If [the] FDA were to permit preliminary claims about such a multitude of associations, the agency believes that ultimately what would be lost is the confidence of most consumers in the validity of all claims that appear in food labeling . . . . Congress, in its enactment of the scientific standard [for foods in conventional form], struck what it believed to be an appropriate balance between the costs and benefits of claims on foods in general. FDA is not aware of any reason to strike a different balance for dietary supplements.

(emphasis added) Id.

Given the expertise of the agency in this particular area, given the fact that Congress had already expressed its approval of the "significant scientific agreement" standard in a different but closely related context, given the very real concerns expressed by the agency about loss of consumer confidence, and given the agency's conclusion that, despite its lengthy rule-making, it "is not aware of any reason" to accept a different standard for dietary supplements than was mandated for conventional foods, the Court concludes that the choice made by FDA was reasonable, and not arbitrary or capricious. As our Court of Appeals noted a long time ago, where the agency decision turns on issues requiring the exercise of technical or scientific judgment, it is essential for judges to "look at the decision not as the chemist, biologist, or

statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality." Ethyl Corp., 541 F. 2d at 36.

Plaintiffs contend that adoption of the "significant scientific agreement" standard violates both the NLEA and the APA because the statute specifically states that dietary supplements are not subject to subparagraph (3) of § 343(r), and that therefore a different standard or procedure must be established by regulation of the Secretary. Thus, Plaintiffs pose an issue of pure statutory interpretation which is governed by the two-step analysis set forth in Chevron USA Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843-45 (1984).

Under the Chevron test, in order to hold FDA's interpretation of its statute erroneous, "we would have to conclude that its interpretation either ran athwart a clear mandate of Congress, or was an unreasonable one." Troy Corporation v. Browner, 120 F.3d 277, 283 (D.C.Cir. 1997). Chevron requires, first, that the court look to the plain meaning of the statute to determine whether Congress has spoken to the precise question at issue. Chevron, 467 U.S. at 842. If it has, then the court must give effect to the clearly expressed intent of Congress. Id. at 842-43. Second, if the statute is silent or ambiguous on the issue, the agency's interpretation should be upheld so long as it is a "permissible construction of the statute." Id. at 843. A court "need not

conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question originally had arisen in a judicial proceeding." Id. at 843 n.11.

Turning to the first question the Court must address, whether the statutory language is clear on its face, there is no doubt that the first prong of Chevron is satisfied. The language of Section 343(r)(5)(D), providing that health claims made with respect to dietary supplements "shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such a claim, established by the regulation of the Secretary" (emphasis added), clearly authorizes the Secretary to choose whatever standard she finds appropriate. The statutory language contemplates that the standard could be the same or stronger than the standard for conventional foods adopted by Congress in Section 343(r)(3).

Moreover, the statute and legislative history clearly demonstrate that Congress spoke to the precise question at issue, and delegated full authority to the Secretary, in the exercise of her agency's scientific and professional expertise, to adopt whichever standard the agency deemed most appropriate. As the House Floor Manager stated, "FDA is given the discretion to define both the procedure and the standard because the principals in the Senate could not agree." See 136 Cong. Rec. H12953 (October 26,

1990).[7] Thus, "[i]f employment of an accepted canon of construction illustrates that Congress had a specific intent on the issue in question, then the case can be disposed of under the first prong of Chevron." Michigan Citizens for an Indep. Press v. Thornburgh, 868 F.2d 1285, 1292-93 (D.C. Cir.) (emphasis in original), aff'd by equally divided Court, 493 U.S. 38 (1989).

In challenging FDA's adoption of the "significant scientific agreement" standard, Plaintiffs focus on the language in § 343(r)(5)(D) which states that health claims "made with respect to a dietary supplement...shall not be subject to subparagraph (3) . . .". Their argument is that the statute, in directing FDA to establish a standard by which to judge the validity of dietary supplement health claims, precludes the agency from adopting the same standard which Congress already adopted in § 343(r)(3). However, that is simply not what the statute says. Rather, its clear import is that upon initial consideration of the issue, health claims for dietary supplements shall not be evaluated under subparagraph 3 where Congress has mandated use of the "significant scientific agreement" standard, but that the agency shall proceed under subparagraph 5 to hold a rulemaking and determine, in its independent judgment and the exercise of its administrative

[7] While ordinarily legislative history is not referred to at Chevron step one, "we may consider a provision's legislative history in the first step of Chevron analysis to determine whether Congress' intent is clear from the plain language of the statute". Ethyl Corp. v. EPA, 51 F.3d 1053, 1062-63 (D.C. Cir. 1995).

discretion and expertise, what constitutes the most appropriate and reasonable standard for determining the scientific validity of health claims for dietary supplements.

Even if, under the first step of the Chevron analysis, it was determined that the statutory language was not clear on its face, it would be perfectly clear under the second step of that analysis that the agency's construction of the statute is both permissible and reasonable. Moreover, the legislative history of this provision fully supports this conclusion. As noted above, Congress was unable to agree on a substantive standard for judging the validity of health claims for dietary supplements. Because of this lack of consensus, Congress delegated the task to the FDA. The House Floor Manager explained that "[i]t is obvious...that the agency could adopt the same procedure and standard that Congress has adopted for disease claims on food...[I]t is also obvious that it could adopt a stronger standard...There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims. The potential is just as great for vitamins as it is for other products." 136 Cong. Red. H12953 (October 26, 1990). Thus, it is clear from the statement of the House Floor Manager of the legislation, that Congress was delegating to the agency the choice amongst various alternatives. "Under Chevron, the agency is entitled to deference in its reasonable interpretation of an ambiguous statute", Troy, 120 F.3d at 290.

In sum, the agency has provided an adequate rationale for its adoption of the "significant scientific agreement" standard for determining the validity of health claims for dietary supplements, and therefore its decision was neither arbitrary nor capricious. In addition, its interpretation of the applicable statute was correct, using either a one-step or two-step analysis under Chevron, and therefore its decision was not contrary to law.

B. Neither the "Significant Scientific Agreement" Standard for Dietary Supplements, Nor the Refusal to Allow the Health Claims Sought by Plaintiffs Violates the First Amendment

In Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980), the Supreme Court established a four-part analysis for evaluating legislative restrictions on commercial speech. See also 44 Liquormart, Inc. v. Rhode Island, 1996 WL 241709 at 9 (1996); Florida Bar v. Went For It, Inc., 515 U.S. 618, 623-24 (1995); Rubin v. Coors Brewing Co., 514 U.S. 476, 482 (1994). First, the Court must "determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading." Central Hudson, 447 U.S. at 566. Second, the Court must decide "whether the asserted governmental interest is substantial. If both inquiries yield positive answers, [the Court] must determine whether the regulation directly advances the governmental interest asserted". Id. And finally, the Court must determine "whether it is not more extensive

than is necessary to serve that interest." Id.

Plaintiffs claim first, that the "significant scientific agreement" standard, on its face, cannot meet the Central Hudson test, and second, that the standard as applied, to folic acid, antioxidant vitamins, omega-3 fatty acids, and dietary fiber, also fails the Central Hudson test because it is overbroad, a prior restraint on speech, and impermissibly restricts commercial speech.

As a preliminary issue, it must be noted that there is no support for Plaintiffs' contention that the "significant scientific agreement" standard is overbroad and a prior restraint on commercial speech. First, the Supreme Court has held in Board of Trustees of the State Univ. of N.Y. v. Fox, 492 U.S. 469, 481 (1989), that the overbreadth analysis does not apply to commercial speech. See also Bates v. State Bar of Arizona, 433 U.S. 350, 380-81 (1977). Second, there is no case law holding that the prior restraint doctrine is applicable to commercial speech. Moreover, given the cautionary language in Central Hudson, 447 U.S. at 571 n. 13[8] and Virginia Pharmacy Bd. v. Virginia Citizens Consumer Council, 425 U.S. 748, 771-72 n. 24 (1976), the Court finds it very doubtful that the doctrine is applicable in this case. Finally, even if the doctrine of prior restraint were applicable, the regulations at issue are not a blanket prohibition against

[8] In Central Hudson, the Court "observed that commercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it", citing similar language in Virginia Pharmacy Bd..

distribution by Plaintiffs of substantive information about the claims they wish to make. The only restriction placed on distribution of the information occurs when the health claims are included on the labels of dietary supplements being sold to the general public.

1. The Commercial Speech Covered By The "Significant Scientific Agreement" Standard And The Four Individual Health Claims Proposed By Plaintiffs Is Misleading.

Plaintiffs make First Amendment challenges to both the general standard adopted by the FDA and its specific decisions disapproving the four health claims sought by Plaintiffs. Plaintiffs argue that the health claims they seek to include on dietary supplement labels are truthful and not misleading. The FDA argues that any health claim which can not meet the "significant scientific agreement" standard is misleading to consumers, and in particular, as applied to these four health claims. The failure to meet the standard makes the claims misleading because they have not been scientifically validated. Therefore, the protections of the First Amendment are not applicable.

For a health claim label not to be inherently misleading the FDA must find it to be supported by significant scientific agreement. A statement is "inherently" misleading when "the particular method by which the information is imparted to consumers is inherently conducive to deception and coercion." Peel v. Attorney Registration and Disciplinary Comm'n, 496 U.S. 91, 112

(1990). A health claim is inherently misleading when the public lacks the necessary knowledge to evaluate it, In re R.M.J., 455 U.S. 191, 202 (1982), and when it is not subject to reliable verification through a consumer's personal experience. American Home Prod. v. FTC, 695 F.2d 681, 698 (3d Cir. 1982). Specially, the FDA has found that health claims that rely on preliminary data, hypothetical associations, or anecdotal evidence, make an "ill-defined association" in the mind of consumers that is not based on solid, reliable, scientific data.

Regarding the health claims proposed by Plaintiffs for antioxidants, fiber, and omega-3 fatty acids, the FDA examined evidence, engaged in a lengthy rule making, and, following notice, comment, and extensive review, determined that there was not significant scientific agreement that those health claims were valid. See 58 Fed. Reg. 53298, 56 Fed. Reg. 60566, 60579-82 (II Supp. Rec. 284, 297-300) and 58 Fed. Reg. 2537, 2549-51 (II Supp. Rec. 301, 313-15) (fiber); 58 Fed. Reg. 53303, 56 Fed. Reg. 60663, 60677-89 (II Supp. Rec. 383, 397-409) (omega-3 fatty acids); 58 Fed. Reg. 53302, 2622, 2641-60 (antioxidants) (II Supp. Rec. 468, 472, 473).

As to anti-oxidants, the FDA found that while populations with diets rich in fruits and vegetables experience lower rates of some cancers, it was not possible to determine specifically that it is the antioxidant vitamins contained in fruits and vegetables which are responsible for this effect or to rule out the possibility of

significant protective effects from other components in these foods. 58 Fed. Reg. at 53302. As to fiber, the FDA concluded that, although there was a relationship between diets rich in fiber-containing foods and a reduced risk of cancer, none of the studies provided evidence of an independent contribution from fiber itself to cancer risk reduction. 58 Fed. Reg. at 53298. Finally as to omega-3 fatty acids, the FDA concluded, after reviewing 350 scientific studies on omega-3 fatty acids and coronary heart disease, that there was no significant scientific agreement that the consumption of omega-3 fatty acids would reduce the risk of coronary heart disease. 58 Fed. Reg. 2707-2714.

The health claim related to folic acid was denied because the FDA found the claim to be neither scientifically valid nor true. The FDA explained in 58 Fed. Reg. 53282 (I Supp. Rec. 266) that:

> In § 101.79(c)(2)(i)(H), the agency is proposing that a health claim not state that a specified amount of folate is more effective in reducing the risk of NTDs [neural tube defects] than a lower amount (e.g. 100 mg). This proposed requirement is consistent with data showing that reduction in risk of NTDs has been associated with general dietary improvement (which is assumed to increase folate intake by unspecified amounts).

This conclusion was based on studies showing that the statement regarding folic acid and neural tube defects was false. See, e.g., 61 Fed. Reg. 8758-60; "Periconceptual Folic Acid Exposure and Risk of Occurrent Neural Tube Defects," JAMA, 269: 1257-61, 1993 (Ref. 26 in the document that begins at 58 Fed. Reg. 53254 (I Supp. Rec. 238); 58 Fed. Reg. at 53259 (I Supp. Rec. 243); "Multivitamin/Folic

Acid Supplementation in Early Pregnancy Reduces the Prevalence of Neural Tube Defects," JAMA, 262; 2847-52, 1989 (Ref. 6 in document that begins at 58 Fed. Reg. 53254 (I Sup. Rec. 238); 58 Fed Reg. 53259 (I Supp. Rec. 243).

Given that each of these claims failed to meet the "significant scientific agreement" standard, the FDA found each to be inherently misleading. As such, they are not subject to protection under the First Amendment and the FDA may prohibit their use on labels of dietary supplements.

Defendants have satisfied the Central-Hudson test for both the "significant scientific agreement" standard and the four rejected health claims.[9] Finally, in the unlikely event that Plaintiffs were able to propose health claims that were not misleading, even though they could not meet the "significant scientific agreement" standard, that standard is a permissible restriction on commercial speech because it satisfies the remaining prongs of the Central Hudson test.

2. The Asserted Government Interest Is Substantial

The government has a substantial interest in ensuring that

[9] Plaintiffs also argue that the FDA's decision denying the four proposed health claims was arbitrary, capricious, an abuse of discretion, and contrary to law. This Court has already found that the "significant scientific agreement" standard does not violate the NLEA or APA and that the FDA appropriately used the "significant scientific agreement" standard to evaluate the proposed health claims. As already discussed, the FDA's determination to reject the four proposed claims is supported by the record and its determination is entitled to deference.

labels on dietary supplements are truthful and non-misleading to protect the health and safety of consumers. The legislative history of the NLEA clearly states that Congress was concerned with preventing consumer fraud and promoting public health. 59 Fed. Reg. 402-3 (1994). The FDA was also concerned with the loss of consumer confidence if it failed to ensure that the labels on dietary supplements were accurate. Id. at 403. As the Second Circuit stated:

> The legislative history of these provisions reveals that substantial governmental interests drive the NLEA and implementing regulations: preventing the spread of unsubstantiated health claims on labels so that consumers may not be deceived and follow unsound health practices; ensuring the reliability of scientific information disseminated in connection with the sale of dietary supplements; and protecting consumers from being induced to purchase products by misleading information on labels.

Nutritional Health Alliance, et al. v. Shalala, et al., 953 F. Supp. 526, 529 (S.D.N.Y. 1997); National Council For Improved Health, et al. v. Shalala, et al., 893 F. Supp. 1512, 1517-18 (D. Utah 1995). The second prong of the Central-Hudson test is clearly met by the regulation.

3. The Regulation Directly Advances the Governmental Interest Asserted

The FDA regulation requires that health related nutrient-disease claims be supported by significant scientific agreement. As such, the regulation directly advances the government's interest in preventing consumer fraud by unsupported health claims.

Consumers cannot be expected to do research and analyze

voluminous preliminary and often conflicting scientific studies to determine whether a health claim is valid. Comprehending this information requires the requisite knowledge and technical expertise which the FDA obviously possesses. The truthfulness of health claims is not verifiable through individual experiences. A person could spend their entire life taking a dietary supplement, and never know whether that supplement actually made a difference in the quality or length of their life. Most health claims must be verified on the basis of long-term, randomized, controlled studies of large numbers of individuals. The experiences of a single consumer can, obviously, never serve to scientifically verify the medical efficacy of a particular dietary supplement.

Consequently, Congress' determination that FDA should establish a standard for evaluating the health claim labeling of dietary supplements directly advances the governmental interest in ensuring that such labeling be truthful and not misleading. Moreover, the substance of the "significant scientific agreement" standard is designed to accomplish precisely that goal. Therefore, the regulation satisfies the third prong of the Central Hudson test.

4. The Regulation Is No More Extensive Than Necessary To Serve The Government's Interest

In Fox, supra, the Supreme Court stated that:

> [i]n requiring [regulation of expressive conduct] to be "narrowly tailored" to serve an important or substantial state interest, we have not insisted that there be no

> conceivable alternative, but only that the regulation not "burden substantially more speech than is necessary to further the government's legitimate interests."

492 U.S. at 478 (quoting Ward v. Rock Against Racism, 491 U.S. 781 (1989). The fit between the governmental interest and the legislative means chosen "need not be perfect, but simply reasonable." Id. at 480 (citations omitted). The FDA's objective is to protect consumer health and well being by preventing the dissemination of unsupported or insubstantial scientific information on dietary supplement labeling. The regulation is sufficiently narrowly tailored by Congress to affect only the label itself or materials directly attached to the label of the dietary supplement. As such, the regulation is no broader than necessary to protect the public health and prevent consumer fraud.

Although Plaintiffs voice a legitimate desire to inform the public about what they believe to be the nutritional benefits of dietary supplements, the ability of the public to obtain this information is not substantially impinged upon by the FDA regulation. The NLEA applies only to health related claims affixed to labels and the actual labeling. The FDA regulations at issue do not apply, for example, to reports of scientific research, magazine articles, newspapers, scientific journals, or any other publications that are disseminated to the public in a non-commercial speech context. Nor, it must be remembered, do the regulations restrict the sale of dietary supplements; they affect only the sale of those products that assert health claims in their

labeling. For these reasons, the Court concludes that the FDA regulation is sufficiently narrow to serve only the government's interest in protecting consumers from fraud and misinformation and in protecting their health.

The "significant scientific agreement" standard and the rejection of the four misleading claims meet the Central Hudson test. The standard adopted by the FDA ensures that claims made are scientifically valid, not misleading, and understandable to the public. The petition procedure assures that unfounded health claims do not flood the market. The regulation is narrowly tailored to balance the elimination of unfounded claims with allowing valid ones. Accordingly, the regulations are a permissible restriction on commercial speech and do not violate the First Amendment.

C. The "Significant Scientific Agreement" Standard for Dietary Supplements Does Not Violate the Fifth Amendment

Plaintiffs argue that the "significant scientific agreement" standard is void for vagueness because it fails to set forth a clear standard of review. As the FDA makes clear in its pleadings, it is not possible to spell out the kind of detailed, mathematically precise definition of "significant scientific agreement" which Plaintiffs seek. When determining whether there is significant scientific agreement, many factors must be examined. Mere numbers of studies do not paint the whole picture. For example, the FDA must consider the duration of the studies, the

number of persons monitored, the reliability of procedures followed, and any flaws in the studies. These are all factors that only the FDA, with its scientific expertise, can decide on a case-by-case basis.

As discussed above, the regulation is clear in establishing the necessary standard and procedure that must be followed in order to place a health claim on a dietary supplement label. The regulation provides that if Plaintiffs want to distribute dietary supplements bearing a health claim, they must have the claim approved by the FDA through a regulation, and the claim must comply with that regulation.

The "significant scientific agreement" standard adopted by the FDA is the same one that Congress adopted for conventional foods. The FDA deals on a routine basis with complex scientific data which is within the agency's expertise. No one is more qualified for the task of determining whether significant scientific agreement exists among experts, than the experienced scientists at the FDA. In sum, the "significant scientific agreement" standard is not void for vagueness.[10]

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[10] Plaintiffs failed to offer any cases on point, in support of their position. Courts have consistently relied on FDA's special expertise in deciding scientific issues relating to labeling, without finding that the regulations violated the Fifth Amendment for being void for vagueness. United States v. An Article of Device ... Diapulse, 650 F.2d 908, 910 (7th Cir. 1981); Unites States v. Diapulse Corp. of America, 457 F.2d 25, 29 (2d Cir. 1972); United States v. Allan Drug Corp., 357 F.2d 713, 719 (10th Cir. 1966) cert. denied, 385 U.S. 899 (1966).

IV. Conclusion

The FDA Final Rules did not violate the NLEA, APA, First Amendment or Fifth Amendment. The FDA carried out Congress' mandate when it adopted the "significant scientific agreement" standard for dietary supplements, and when it used that standard to review the four specific health claims denied in this case. The FDA provided adequate reasons for adopting the standard and its decision was neither arbitrary nor capricious. Additionally, its interpretation of the statute was correct and not contrary to law. The "significant scientific agreement" standard satisfied the Central Hudson test and therefore did not violate the First Amendment. Further, the four proposed health claims rejected in this case were inherently misleading, and therefore not protected by the First Amendment. Finally, the "significant scientific agreement" standard did not violate the Fifth Amendment because it sets out a specific and clear standard of review—-a case-by-case review of the scientific evidence to determine whether there is significant scientific agreement among the experts that the proposed health claim is valid. For the reasons discussed above, Plaintiffs' Motion for Summary Judgment is **denied** and Defendants' Motion to Dismiss is **granted**. An Order will issue with this Opinion.

_____ _____

Date Gladys Kessler

United States District Judge

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